K010309

APR 1 8 2001

EXHIBIT 2

510(k) Summary of Safety and Effectiveness

Mutoh America Co., Ltd.
20 William Street, #165
Wellesley, MA 02481
Tel 781-416-4030
Fax 781-416-4035
Contact: Tony Murouchi, President

January 30, 2001

1. Identification of the Device:
   Proprietary-Trade Name: "Sonopet Model UST-2001" Ultrasonic Surgical Aspirator.
   Classification Name/Product Code: LFL
   Common/Usual Name: Surgical Aspirator

2. Equivalent legally marketed device: This product is similar in design and identical in function to the CUSA Excel Ultrasonic Surgical Aspirator System K981262.

3. Indications for Use (intended use) The Sonopet Model UST-2001Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery.

4. Description of the Device: The Mutoh "Sonopet Model UST-2001" Ultrasonic Surgical Aspirator System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissues while preserving vessels, ducts and other delicate structures. The Sonopet Model UST-2001 System consists of a console which provides control and power functions, a surgical handpiece which provides ultrasonic mechanical energy to the surgical site, a titanium handpiece tip and flexible irrigation flue, and a suction/irrigation system

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5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	CUSA Excel Ultrasonic Surgical Aspirator System K981262	"Sonopet Model UST-2001" Ultrasonic Surgical Aspirator
Indications for use	For use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery	SAME
Where used	Hospitals	SAME
Frequency	23 kHz and 36 kHz	25 kHZ and 34 kHz
Maximum Tip Amplitude	Up to 355 microns	Up to 350 microns
Oscillation System	Piezoelectric	SAME.
Power Source	120 VAC 50-60~	SAME

6. Conclusion: In all material respects, the "Sonopet Model UST-2001" Ultrasonic Surgical Aspirator is substantially equivalent to one or more products of similar description. Testing, certifications, and clinical experience demonstrates that the device is equivalent to the CUSA Excel Ultrasonic Surgical Aspirator System currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2001

Mutoh America Co., Ltd.
C/O Kamm and Associates
Mr. Daniel Kamm
Regulatory Engineer
P.O. Box 7007
Deerfield, Illinois 60015

Re: K010309
Trade/Device Name: Sonopet Model UST-2001 Ultrasonic Surgical Aspirator
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 30, 2001
Received: February 1, 2001

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11. Indications for Use

510(k) Number K010309

The Sonopet Model UST-2001Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery. For use by skilled physicians.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010309